

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND
IRBESARTAN PRODUCTS LIABILITY
LITIGATION

MDL No. 19-2875 (RBK)

This document relates to:
All Actions

SPECIAL MASTER ORDER NO. 77

Pending in this matter is the request by the ZHP Defendants¹ to redact information from the “Final GMP Inspection Report,” issued by the European Medicines Agency (“EMA”) and the European Directorate for the Quality of Medicines & HealthCare (“EDQM”) in connection with a September, 2018 investigation of the contamination of Valsartan by N-nitrosodimethylamine (“NDMA”).² ZHP’s request to redact the Final GMP Inspection Report has a

¹ The ZHP Defendants are Zhejiang Huahai Pharmaceutical Co., Ltd.; Princeton Pharmaceutical Inc.; Huahai U.S. Inc.; and Solco Healthcare US, LLC.

² Valsartan is prescribed for the treatment of high blood pressure. According to an EPA Technical Fact Sheet, “NDMA is a semi volatile organic chemical that forms in both industrial and natural processes. It is member of N-nitrosamines, a family of potent carcinogens.” (“Technical Fact Sheet – NDMA, available at https://www.epa.gov/sites/default/files/2014-03/documents/ffirofactsheet_contaminant_ndma_january2014_final.pdf (Last visited May 22, 2023)).

lengthy history.

Initially, the Report was submitted under seal by Plaintiffs as Exhibit “CC” to Plaintiffs’ April 27, 2021 agenda letter for the April 28, 2021 Discovery Hearing and Case Management Conference (ECF Doc. No. 1189). Plaintiffs submitted the Report under seal because it had been designated as “Protected Information” by the ZHP Defendants under the Confidentiality and Protective Order entered in this matter. Paragraph 31 of the Confidentiality and Protective Order required Plaintiffs to submit it under seal. (ECF Document No. 139.) Following a ruling on another confidentiality dispute, Plaintiffs claimed that the ZHP Defendants had waived confidentiality by not timely moving to seal the Report as required by paragraph 31 of the Confidentiality and Protective Order.³

³ In pertinent part, paragraph 31 provides:

Any documents that a Party wishes to file with the Court during this Action which have previously been designated as “PROTECTED INFORMATION” (or which contain CONFIDENTIAL INFORMATION or RESTRICTED CONFIDENTIAL INFORMATION), and all pleadings and memoranda purporting to reproduce or paraphrase such “PROTECTED INFORMATION,” shall be filed in a manner that preserves the confidentiality of such information. . . . Within ten (10) business days of the completion of briefing related to the filing [of the document under seal], the filing party and Producing Party shall confer to determine whether they can agree upon non-confidential redacted or excerpted pages of materials containing “PROTECTED INFORMATION” to attach to the filing. in place of the Bates number designations or redacted materials. If the parties are unable to reach an agreement, *then the designating party*

In Special Master Order No. 49, I concluded that, in light of an order that stayed deadlines for motions to seal (ECF No. 1269), the ZHP Defendants had not waived their confidentiality designations by not moving sooner to seal the documents in question, including Ex. “CC” to Plaintiffs’ April 27, 2021 agenda letter. Special Master Order No. 49, issued on October 25, 2021, directed the parties to meet and confer with respect to a multitude of confidentiality designations made by the ZHP Defendants, including the Final GMP Inspection Report.

By letter filed on December 17, 2021 (ECF Doc. No. 1823), the ZHP Defendants re-asserted their confidentiality designation for the entire Final GMP Inspection Report. Oral argument concerning the ZHP Defendants’ confidentiality designation for the Final GMP Inspection Report and thirteen other documents was scheduled for January 5, 2022, later extended to January 18, 2022. (ECF Doc. Nos. 1826, and 1874 at 2.)

During the argument presented on January 18, 2022, the parties were directed to brief the question of whether the Final GMP Inspection Report was publicly accessible pursuant to a Freedom of Information-type request. If the

must file a motion to seal the materials containing “PROTECTED INFORMATION” pursuant to the requirements for doing so as set forth in Local Rule 5.3(c), and within thirty (30) days of the completion of briefing related to the original motion, or else waive confidentiality as to the materials containing “PROTECTED INFORMATION” at issue.

document was not accessible upon request, the ZHP Defendants were directed to submit a proposed redacted document as I had concluded that the entire Report should not be sealed. By letter briefs filed on February 8, 2022, the parties took opposite positions on whether the Final GMP Inspection Report was publicly accessible. (*See* ECF Doc. No. 1906 (Defense letter) and ECF Doc. No. 1907 (Plaintiffs' letter).) By Special Master Order No. 70, oral argument on the matter was again scheduled, this time for September 8, 2022. (ECF Doc. No. 2148.)

During the argument presented on September 8, 2022, I made it clear that the redactions that had been proposed to the Final GMP Inspection Report by predecessor counsel for the ZHP Defendants were too expansive, covering matters that may be embarrassing to the ZHP Defendants but which did not concern competitively sensitive information.⁴ New counsel requested and was granted an opportunity to submit a revised redacted Final GMP Inspection Report, with the redactions being much more limited. Once again, Plaintiffs objected to the redactions. (ECF Doc. No. 2164.)

Plaintiffs point out that the latest redactions to the Final GMP Inspection Report are not supported by an affidavit of an individual with personal knowledge

⁴ New counsel entered his appearance on behalf of the ZHP Defendants on September 1, 2022. (ECF Doc. No. 2156.)

explaining why the redactions are necessary to avoid substantial harm.⁵ That failure is fatal to the request to redact this document. *See Schatz-Bernstein v. Keystone Food Products, Inc.*, 2009 WL 1044946, at *2 (D. N.J., April 17, 2009) (denying motion to seal supported only by a certification by counsel that the moving party ““would suffer substantial and specific harm”” that was not otherwise specified). Just as in *Schatz-Bernstein*, the ZHP Defendants’ “contentions regarding the alleged harm they would suffer from the disclosure . . . are general, overbroad and conclusory. Defendants do not cite to any specific examples of harm they would suffer. Defendants’ averments simply do not satisfy their burden of proof under [Local] Rule 5.3 and applicable case law.” *Id.*

Although consideration of this matter could end with the finding that the ZHP Defendants have failed to substantiate their proposed redactions, the gravity of the matter compels examination of each of the proposed redactions. The redactions will be addressed by category, with the first category being the names of inspectors and other officials involved in examining the contamination of Valsartan.⁶

⁵ The ZHP Defendants were required to make “a particularized showing that disclosure will cause a “clearly defined and serious injury” *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 786 (3d Cir.1994). This they have not done.

⁶ The names of the inspectors and other government officials are found at Bates Numbers ZHP0232473, ZHP02324767, and ZHP02324769.

The ZHP Defendants have not articulated any competitive harm flowing from disclosure of the names of those involved in preparing the Final GMP Inspection Report. The official involved are public servants who have not claimed any right to anonymity. Accordingly, the redactions appearing on the Report at Bates Nos. ZHP0232473, ZHP02324767, and ZHP02324769 must be removed.

There is also no apparent reason for redacting the names of ZHP customers, and the public interest in knowing what companies may have received contaminated Valsartan from the ZHP Defendants is overwhelming. The redactions on the Report at Bates Nos. ZHP02324742, ZHP02324744-48 and ZHP02324772-73 must be eliminated.

No justification for redacting the references to amines, potable water, tetrazole ring formation, and the other items redacted on Bates Nos. ZHP02324748-49 is readily apparent, and those redactions must be eliminated. The same conclusion is reached with respect to the technical information concerning production processes described at Bates Numbers ZHP02324750, 51, 52, 53, 56, 57, 58, 60, 61, 62, 63, 64, 70, 71, 72, 74, 75, 77. Although this information could be competitively sensitive, no evidentiary basis for making this conclusion has been presented.⁷

⁷ Notably, during the January 18, 2022 argument I identified several pages of information that appeared to me to be competitively sensitive, starting at ZHP 02324779 through ZHP 02324787, but the ZHP Defendants did not propose

In summary, although the ZHP Defendants commendably reduced the number and volume of proposed redactions, they have not justified with competent evidence a single one of their proposed redactions. Accordingly, **IT IS HEREBY ORDERED THAT** the Final GMP Inspection Report, filed under seal at ECF Doc. No. 1189, be unsealed and made available to the public. Unless appealed, this Order will be effective 22 days after the filing and service of this Order. *See* Fed. R. Civ. P. 53(f)(2) (“A party may file objections to--or a motion to adopt or modify--the master's order, report, or recommendations no later than 21 days after a copy is served, unless the court sets a different time.”).

Date: May 23, 2023

s/ Thomas I. Vanaskie
Hon. Thomas I. Vanaskie (Ret.)
Special Master

redacting any information from those pages. That fact illuminates the wisdom of requiring the proponent of redactions to provide an evidentiary basis for keeping from public view documents that are part of a court record, to which a presumption of public access attaches. *See In re Avandia Mktg., Sales Practices and Products Liab. Litig.*, 924 F.3d 662, 672-73 (3d Cir. 2019).